



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 18 2006

Covalon Technologies Ltd.
c/o Mr. Jacques Lemmetti
Executive Chairman
2033 Iverson Lane
Waxham, North Carolina 28173

Re: K060804

Trade/Device Name: Collagran wound dressing, Collagran Ag wound dressing

Regulation Number: Unclassified

Product Code: FRO

Dated: March 23, 2006

Received: March 27, 2006

Dear Mr. Lemmetti

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

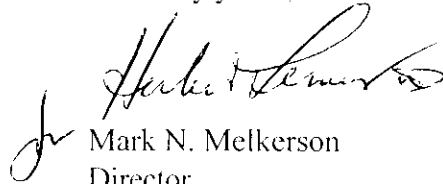
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over a printed name. To the left of the signature is a small, stylized initial "J".

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1K060804

Indications for Use Statement

**510(k)
Number**
(if known)

Device Name Collagran wound dressing
Collagran Ag wound dressing

**Indications
for Use** The Collagran wound dressing and Collagran Ag wound dressing are
intended to be used for the following conditions:

the management of full and partial thickness wounds including:

- pressure ulcers,
- diabetic ulcers,
- ulcers caused by mixed vascular etiologies,
- venous ulcers,
- first and second degree burns,
- donor and graft sites,
- abrasions and lacerations,
- dehisced surgical wounds,
- traumatic wounds healing by secondary intention

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

[Signature]
Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K060804

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